

REMARKS/ARGUMENTS

Claims 6 and 8-9 remain in this application. Claim 7 has been canceled without prejudice. For the reasons set forth below, it is submitted that claims 6 and 8-9 are in condition for allowance and allowance of the application is respectfully requested.

References Submitted in an IDS

In the Office Action, the Examiner maintains that the IDS filed on August 29, 2003, fails to comply with 37 CFR 1.98(a)(2) which requires a legible copy of each of the references. In particular, the Examiner contends that WO 95/13837 and WO 95/14142 are missing and not of record in the parent application.

In response, Applicant notes that the IDS filed on August 29, 2003 included a typographical error, wherein the Deniega et al. reference was mistakenly listed as WO 95/14142, instead of WO 95/14172. In addition, Applicant also notes that the Deniega et al. (WO 95/14172) reference claims priority to U.S. Application Ser. No. 08/153,755 (now U.S. Pat. No. 5,460,493), which was previously cited in the IDS filed August 29, 2003. A Supplemental Information Disclosure Statement, including copies of the Deniega et al. (WO 95/14172) and Chapman et al. (WO 95/13837) references, is submitted herewith. It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO/SB/08A (08-03) with initials or other appropriate marks, and that the references be made of record as cited references in the application.

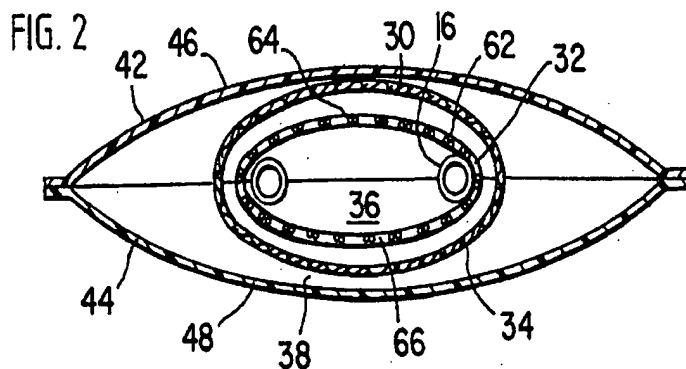
Rejections under 35 USC §102(e)

In the Office Action, claim 6 was rejected under 35 U.S.C. §102(e) as being unpatentable over *Japuntich* (U.S. Pat. No. 5,695,489). For the reasons set forth below, Applicant respectfully traverses the rejection of claim 6 over the art and respectfully submits that claim 6 defines patentable subject matter over the prior art.

Claim 6 of the present invention recites, in part, a flexible plastic bag or reservoir having an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag. Because the integral coarse filter

is semi-rigid, it holds open a path through the otherwise collapsed bag or reservoir for the cells to move up to the top outlet port.

In contrast to the present invention, the *Japuntich* reference discloses a flexible device having a filtering means 24 which includes a "filtering material 30...in the shape of a tube" and "a separating means 32 for preventing the filtering material 30 from collapsing upon itself." (See Col. 3, lines 61-61 and Col. 3, lines 7-9, respectively) As best seen in Figure 2 (reproduced below), the *Japuntich* device requires an additional component – i.e., the separating means 32 - in order to prevent the flexible device/bag from collapsing upon itself and thereby preventing blood from flowing through the filtering material.



Moreover, *all* disclosed embodiments of the *Japuntich* reference include the additional component of a separating means 32 for preventing the filtering material 30 from collapsing upon itself. For example, as shown in "FIG. 3, which is an alternate embodiment of the invention...the separating means 32 is formed using multiple rings 70-72...to prevent the filtering material 30 from collapsing upon itself...In another embodiment of the invention, as illustrated in FIG. 4, the separating means 32 is formed using a vertically extending bar...to prevent the filtering material 30 from collapsing upon itself...In yet another embodiment of the invention, as illustrated in FIG. 5, the separating means is formed using a pair of diagonally extending crossed bars 84, 86...to prevent the filtering material 30 from collapsing upon itself...In yet another embodiment of the invention, illustrated in FIG. 6, the separating means 32 may be

formed using an external supporting frame 88...to prevent the filtering material 30 from collapsing upon itself." (See Col. 4, lines 38-64)

Therefore, nowhere does the *Japuntich* reference disclose or suggest a flexible device having an integral coarse filter comprising only a tube of semi-rigid, non-collapsible plastic mesh which prevents the bag from collapsing upon itself as in the presently claimed invention.

Rejections under 35 USC §103

In the Office Action, claims 8-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Japuntich* in view of *Hauer et al.* To establish a prima facie case of obviousness, the Examiner must meet three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the teachings of the references. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (see MPEP §2143.03).

Although the Examiner conceded that claims 8-9 essentially differ from the blood bag of *Japuntich* in reciting a bubble trap at the top comprising plastic tubing extending from the top port into the bag inside the mesh tube, the Examiner maintained that it would have been obvious to a person of ordinary skill in the art to modify the blood bag of *Japuntich* to incorporate a tube extending from the top port into the bag of *Japuntich* inside a mesh filter to remove air as suggested by *Hauer et al.* This rejection must fail for at least the same reasons as set forth in the traversal of claim 6 under 35 U.S.C. §102(e) above. In short, the *Japuntich* reference fails to disclose or suggest the elements of claim 8, namely, a flexible plastic bag or reservoir having an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag, wherein the filter holds open a path through the otherwise collapsed bag or reservoir for the cells to move up to the top outlet port. As such, the *Japuntich* reference fails as a primary reference at the outset.

The *Hauer et al.* reference also fails to disclose or suggest the above-referenced elements of claim 8. The *Hauer et al.* reference discloses a collapsible bag 14 having a

filter 36 attached to the intake port 34 and a stent 16 assembled onto the bag to hold it in distended form. As best seen in Figures 1-4, the *Hauer et al.* device requires an additional component – i.e., the stent 16 - in order to prevent the flexible device/bag from collapsing upon itself and thereby preventing blood from flowing through the filtering material during the transfer of blood therefrom. In particular, as disclosed in Col. 3, lines 54-66, “the bag 14 functions in a manner equivalent to that of a rigid collecting bottle, since it is held in distended form by the stent 16.” Therefore, nowhere does the *Hauer et al.* reference disclose or suggest a collapsible bag having an integral coarse filter comprising only a tube of semi-rigid, non-collapsible plastic mesh, wherein the filter holds open a path through the otherwise collapsed bag for the cells to move up to the top outlet port which prevents the bag from collapsing upon itself, as in the presently claimed invention.

Therefore, at a minimum, neither the *Japuntich* patent nor the *Hauer et al.* patent, either alone or in combination, teach or suggest a device that includes a collapsible bag having an integral coarse filter comprising only a tube of semi-rigid, non-collapsible plastic mesh which prevents the bag from collapsing upon itself, wherein the filter holds open a path through the otherwise collapsed bag for the cells to move through the outlet port. For the reasons stated above, it is respectfully submitted that claim 8 is not obvious over the *Japuntich* and *Hauer et al.* references. In addition, claim 9, which is dependent to claim 8, further distinguishes over the prior art and thus is independently patentable over claim 8.

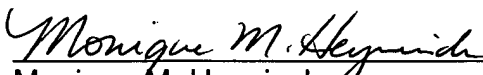
In view of the foregoing, it is submitted that all pending claims 6 and 8-9 are in condition for immediate allowance. Accordingly, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

If for any reason direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1329.

Respectfully submitted,
STRADLING YOCCA CARLSON & RAUTH

January 22, 2004


Monique M. Heyninck
Reg. No. 44,763
Tel.: (949) 725-4191

STRADLING YOCCA CARLSON & RAUTH
660 Newport Center Drive, Suite 1600
Newport Beach, CA 92660
Telephone: (949) 725-4000
Facsimile: (949) 725-4100

Customer No.: 31,278